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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,960	02/12/2003	David C. Kaslow	15280-3421PC	6829

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,960	KASLOW ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 13, 14 and 51-62* is/are pending in the application.

4a) Of the above claim(s) *52-56 and 58-62* is/are withdrawn from consideration.

5)☐ Claim(s) *1-3 and 51* is/are allowed.

6)☒ Claim(s) *13, 14 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5/22/2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/01/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 5/01/2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-3,13,14, and 51-62 are pending. Claims 4-12 and 15-50 were canceled, claims 1,2 and 13 were amended and new claims 51-62 were added. Claims 52-56 and 58-62 are withdrawn since they are drawn to unelected subject matter. The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

Election/Restrictions

Applicant's arguments filed 5/01/2006 have been fully considered but they are not persuasive. Applicant argues that the subject matter of groups I-III should be rejoined. Specifically, that claims drawn to the PVS25 polypeptide should be examined with the presently elected invention. However, Unity of Invention was originally broken over WO/89/19936 in the office action of 10/21/05. Applicant's present arguments do provide any evidence or references indicating that this was improper. Therefore the Restriction requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3,13,14,51 and 57 are currently under consideration.

Specification

The objection to the amendment filed 12/29/2003 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, is withdrawn in view of applicant's arguments.

Information Disclosure Statement

Applicant's provision of PTO/SB/08A is noted and entered.

The reference of Hiseada et al. has been considered, but will not be listed on any patent resulting from this application because it was not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Claim Objections

The objection to claim 2 as being dependent upon a rejected base claim is withdrawn in view of applicant's amendments to the claims.

Claim 14 objected to as being in improper form because it depends from canceled claim 16. Accordingly, the claim 14 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn in view of applicant's amendment to the claim.

The rejection of new or amended claims 13 and 57 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Arguments

Applicant's arguments filed 5/01/2006 have been fully considered but they are not found to be persuasive. Applicant argues that the specification teaches that a nucleic acid encoding a PVS25 polypeptide "can" be administered by multiple pathways. However the underlying issue is not whether it is possible to administer a nucleic acid to a subject, but whether the specification provides an enabling disclosure for inducing an immune response against Pvs25 on the surface of *Plasmodium vivax* ookinetes. As previously stated:

In the field of DNA based vaccines, the route of delivery is known to have a significant effect on the efficiency of expression. McCluskie et al. teaches that the route of delivery of DNA vaccine influences immune responses in laboratory animals {McCluskie et al. (1999) Mol. Med. 5:287-300; Abstract}. Specifically, in one study McCluskie et al. only observed antibody responses to injected routes of administration of DNA vaccines and not to non-injected injected routes of administration of DNA vaccines, such as oral routes, sub lingual, inhalation and vaginal wall because of variation in transfection efficiency (Abstract). The specification does not provide any guidance on the specific efficacy of any routes of administration of the claimed vaccine to induce a transmission blocking immune response.

Applicant has not provided any indication where in the specification there is support of inducing an immune response in any susceptible subject with a nucleic acid encoding a PVS25 polypeptide by any route of administration.

Next, applicant argues that the reference of Hisaeda et al. demonstrates the immunization of mice with Pvs25. However, it is noted that Hisaeda et al. only disclose immunizing mice with a PvS25 polypeptide, not a polynucleotide. This is not considered to be persuasive since the art of record indicates that the efficacy of DNA vaccines against parasites is generally unpredictable. As previously stated:

The specification as filed does not provide any guidance on the ability of a nucleic acid encoding a Pvs25 polypeptide to induce any transmission blocking immune response. Example 6 discusses an *in vitro* method of assessing transmission-blocking activity of anti-sera generated from mice immunized by intraperitoneal injection of Pvs-25 or Pvs-28 polypeptides. However, the example does not describe any results of the analysis, such as whether the Pvs-25 or Pvs-28 polypeptides were successful at inducing transmission blocking activity as analyzed by the assay of example 6. Finally, the specification does not provide any guidance on the ability of a nucleic acid encoding a Pvs25 polypeptide to induce any immune response in any susceptible/model organism, such as mouse or a human. The specification does not provide any guidance on the minimum amount of nucleic acid encoding a Pvs25 polypeptide that must be administered in order to induce an immune response.

Additionally:

The problems of DNA vaccines designed to induce an immune response against parasites are numerous. Kofta et al. reported that DNA vaccines have vast differences inefficiency when administered to different strains of mice and rats {Kofta et al. (2001) Vet Parasitology 100:3-12; pg. 7, pgph 4-5}. Kofta reports that when anti-plasmodium DNA vaccines were administered to six different strains of mice produced very different levels of protection, ranging from none to very high (pg. 7, pgph 5). Similarly, it was observed that when the same F. hepatica DNA vaccine was administered to two different strains of rats, protection was observed in only one strain. Further, Kofta teaches that the route of administration of DNA vaccines is very important at producing an immune response, and that the optimal route differs between species for the same vaccine (pg. 6; Section 1.2). Kofta teaches that a Plasmodium DNA vaccine was effective at inducing an antibody response in mice, when administered intramuscularly, but was ineffective when administered to monkeys via the same route. Kofta concludes by stating that the whole picture of DNA vaccination against parasitic infections remains unclear, and much more research into areas such as DNA vaccines in specific target species of animals (pg. 10).

As the above references amply demonstrate the immune responses induced by DNA vaccines against parasites can be unpredictable between different strains of mice. All of

applicant's arguments are directed towards examples involving the administration of a Pvs25 polypeptide, which is qualitatively different than DNA vaccination. DNA vaccination is much less predictable than peptide vaccination, because of the issues associated with expressing enough of the peptide encoded by the vaccine so as to induce an immune response capable of protecting the subject against the parasite. Neither the specification nor the references provided provide any evidence on the ability of any claimed nucleic acid encoding a Pvs25 polypeptide to induce an immune response in any susceptible organism. Therefore the rejection is maintained for reasons of record as set forth above and in the office action of 1/30/06.

Claim Rejections - 35 USC § 102

The rejection of claim under 35 U.S.C. 102(b) as being anticipated by WO 89/10936 (16.11.89), hereafter referred to as Miller et al, is withdrawn in view of applicant's amendments to the claims.

Claims 1,13,14 and 57 are not allowed.

Claims 1, 2, 3 and 51 are allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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